TREATMENT OF HIGH ENERGY LIMB THREATENING LOWER EXTREMITY TRAUMA: AN ETHICAL ARGUMENT FOR AMPUTATION

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Abstract

High-energy lower extremity trauma is a limb and sometimes life-threatening injury. These injuries permanently and irrevocably change a patient's body and life. They can be treated with immediate amputation, reconstruction or delayed amputation after failure of reconstruction. In this paper, I explore the evidence concerning the treatment of mangled extremities, and I identify gaps in the evidence. Based on what is currently known, I argue that physicians not only have an obligation to reframe amputation as a treatment choice rather than a procedure for when all else fails, but also that they have an obligation to promote amputation as the preferred treatment option for these injuries, due to the significant harms and limited benefit of limb reconstruction.

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Contents

1. Introduction

A 25-year-old man is riding his motorcycle when he is struck by a car. His leg is pinned underneath his motorcycle, with exposed muscle and bone. He cannot feel his foot.

A 16-year-old woman is learning to drive with her learner's permit. She fails to stop at a Stop sign and her car is T-boned by a MAC truck. There is pulsing bleeding from an artery as well as visible bone at the site of the broken bones.

A 40-year-old manual laborer is on a roof, working on repairing water damage. He slips and falls off the roof, and lands on his leg which crumples beneath him. As with the two patients above, bone, muscle, tendon, nerves and vessels are all compromised.

A 19-year-old man is serving in the Army in Afghanistan. He steps on a Improvised Explosive Device and his leg is mangled immediately by the explosion.

All of the above injuries are considered severe high-energy lower extremity trauma (HELET), which means that the patient's limb and possibly their life is threatened by the severity of the injury. A limb-threatening injury permanently and irrevocably changes the patient's body and life. These injuries can be treated by limb reconstruction or amputation. In this paper, I will explore the evidence about the treatment of HELET injuries, as well as what is not known about these injuries. I will consider the benefits and harms of each treatment path. Finally, I will argue that the harms of reconstruction require physicians not only to discuss amputation as a treatment

choice rather than a procedure for when all else fails, but also to promote amputation as the preferred treatment option for most HELET injuries.

2. What is Known

2.1. Current Evidence

HELET injuries are by definition limb threatening. They may also be life threatening. They are prone to infection and require a multi-disciplinary care team, often including orthopedic surgeons, plastic surgeons and vascular surgeons. Orthopedic surgeons are often the primary surgeons on the team, due to the frequency of complex fractures.

The optimal treatment for these injuries has long been debated. The Lower Extremity Assessment Project (LEAP) was initiated with the goal of better understanding these injuries. When the LEAP project began, little was known about what influenced decisions about treatment for these injuries. The treatment options can generally be classified as immediate removal of the limb (primary amputation), reconstruction, or amputation after unsuccessful reconstruction (secondary amputation). Reconstruction treatment varies by patient. Fracture stabilization is primary as repairing vessels or grafting skin or muscle onto open wounds requires a stable foundation. Fracture stabilization can be done temporarily or permanently with external fixators, where pins are drilled into the bones and then attached to rings or frames outside the bone to stabilize the fracture. Alternatively, internal fixation may be performed with metal hardware (plates/screws or nails down the inside of the bone). Additionally, little was known about the

long-term outcomes between the surgical options of reconstruction and amputation. The LEAP study published its initial results in 2002, and since then has been defining the conversation about reconstruction or amputation for leg-threatening injuries.[i] [1] Patients who sustained a HELET injury were often previously active and healthy. In the original study, the patients were on average 35 years old, with only a third older than 40 years of age.

The primary conclusion of the LEAP study and its multiple iterations have shown that long-term outcomes (2 years after injury) are equivalent between the two treatment options, though reconstruction required more hospitalizations, more operations and longer rehabilitation in the two years between injury and follow-up.[ii-iii] While the literature demonstrates equivalent outcomes between amputation and reconstruction, surgeons perform more reconstruction than amputation.[iv] Additionally, these studies also showed that the factors that lead surgeons to pursue amputation or reconstruction were highly variable and included both clinical and psychosocial factors, such as the presence of plantar sensation, limb ischemia, soft tissue coverage, fracture pattern, injury score, and patient characteristics.[v] The studies have also shown that injury scoring systems and objective clinical data—such as the lack of plantar sensation—have little bearing on outcome, though surgeons often use them for decision making.[vi]

2.2. Future Directions

[1] According to the criterion put forth by the LEAP project, "high-energy trauma was defined as complicated fractures (Gustilo grade IIIB and IIIC fractures and selected grade IIIA fractures), dysvascular limbs (knee dislocations, closed fractures of the tibia, or penetrating wounds with vascular injury), major soft-tissue injuries (degloving or severe crush or avulsion injury), and severe foot and ankle injuries (Gustilo grade IIIB ankle fractures, all grade III intraarticular fractures of the distal tibia [pilon], and severe hind or midfoot injuries)." In short, these are injuries with fractures due to high-energy, fractures where blood flow was disrupted and vascular repair was needed, fracturers with massive loss of skin/soft tissue requiring plastic surgery, or severe injuries of the back of the foot or middle of the foot, which are known to be devastating due to the small size of the bone, limited muscle coverage and significant forces through these small bones.

Surgical techniques continue to evolve, and it is possible that future advances may change the landscape to advance the care of HELET injuries. Importantly, the LEAP study was specifically focused on the lower extremities. For the upper extremities, the primary innovation over the past decade has been hand transplantation. There have not been similar transplantation efforts for the lower extremity, and the difference in function with the lower extremity being a weightbearing joint makes such attempts unlikely. Nevertheless, the increasingly refined microsurgical techniques for the re-attachment of nerves and vessels utilized in the upper extremities may translate to care of the lower extremities, potentially increasing the range of injuries that may be considered for reconstruction.

The future advances in surgical reconstruction are focused on perfecting existing techniques. In contrast, there has been a significant development in amputation options that may change the calculus around optimal outcomes. Osseointegration is a technique that may alleviate many of the issues with traditional socket prosthetics, whereby the weightbearing occurs through skin and soft tissue with a custom socket to match the amputated limb. Osseointegration was initially developed for dental implants, allowing an alternative to dentures. In an osseointegration procedure, a metal implant is placed into the bone and the prosthesis is then attached directly into the metal through a coupling technique. In lower extremity amputations, osseointegration technology places a prosthesis into the residual bone and it then comes out through the skin, so that weightbearing is directly through the bone onto the prosthesis. An analysis of multiple studies has shown high patient satisfaction and improved quality of life compared to the same patients who had had socket technology.[vii]

As surgical treatments advance, the outcomes for both reconstruction and amputation will both continue to improve. It may be that osseointegration will become the standard of care for lower extremity amputations, and the outcomes will far outstrip reconstruction. Alternatively, microsurgical techniques may evolve to such an extent that reconstruction is the superior technique. At the time of writing this paper, I will assume that the LEAP study data is still correct, and at two years post-injury, there are equivalent outcomes between surgical reconstruction and amputation.

3. What isn't Known

The research around HELET injuries has primarily focused on outcomes, both in physical function and psychological coping. Much less is known about how physicians and surgeons decide on how to treat the extremity. While functional outcomes are equivalent between reconstruction and amputation, surgeons perform more reconstructions than amputations.[viii]

Little is known about the counseling and decision-making process between a patient and physician for a HELET injury. There is no shared decision-making tool to assist patients and their physicians in the conversation about limb reconstruction. The American Academy of Orthopaedic Surgeons has a Clinical Practice Guideline (CPG) to assist surgeons in the management of limb-threatening lower extremity trauma. This guideline supports a shared decision-making process, but the only specific recommendation in support of either treatment is advocating for amputation when further attempts at salvage will increase risk of mortality.[ix]

3.1. Physician Perspectives on Decision Making

There is a dearth of research into physician perspectives on amputation versus reconstruction. In the one study I was able to find on this issue, physicians from the American Society for Reconstructive Microsurgery were surveyed using a standard gamble analysis. Physicians preferred reconstruction to primary amputation, but the Quality Adjust Life Year (QALY; a generic measure of health quantifying both the quality and the quantity of life lived) assigned was only 0.55 over amputation (33.93 vs 33.38, P =0.67); this preference was not statistically significant.

The nearly equivalent QALY physicians assign to reconstruction and primary amputation stand in contrast to the data which demonstrate that substantially more patients undergo reconstruction than amputation. I was unable to find evidence as to why physicians may be performing more reconstructions than amputation. While the reasons for this discrepancy are unknown, I have several hypotheses for why this is the case.

First, I believe some of the preference for reconstruction is driven by a mistaken interpretation of patient autonomy. When a patient sustains a limb-threatening injury, they rightly wish to return to an uninjured state. In my experience, patients and their family will often beg the surgeon to "save the leg." I have heard surgeons defend reconstruction as supporting the patient's decision for reconstruction, but it isn't clear whether this request is grounded in adequate understanding of the injury and treatment options, and therefore whether the request for

limb preservation is autonomous. Additionally, orthopedic surgeons may be uncomfortable having a conversation about amputation, and the surgeon may instead focus on whether reconstruction is at all possible and amputation can be avoided. This approach is supported by the frequent need for delayed or secondary amputation.

Second, the preference for reconstruction may be a result of current training. Orthopedic surgeons are commonly the primary surgeon caring for HELET injuries, and orthopedic trauma training is focused on the restoration of length, alignment and rotation of broken bones. Orthopedic surgical training is increasingly focused on limb reconstruction, including specialized techniques of limb lengthening using complex frames or motorized nails.[x] [2]

Unlike the Civil War era, where good surgeons were defined by the speed of their amputation, current training focuses on the restoration rather than amputation of the limb. In fact, in my own training program, I only performed one amputation with an orthopedic surgeon and instead rotated with a vascular surgeon to gain more experience with amputations.[3] My experience is not unique. As dysvascular limbs (toes and feet without adequate blood flow) have increased due to diabetes and as reconstruction for trauma has become more refined, vascular surgeons (rather than orthopedic surgeons) have begun to perform more and more of the

[2] A lengthening frame outside the body is attached to pins to a bone above and below a cut made in the bone and the patient and physician follow a lengthening protocol, whereby each day they twist pins that lengthen the frame and over weeks to months the bone grows longer. A motorized nail can also be used to lengthen the bone, but unlike the frame, the nail is permanent. Instead of twisting pins that lengthen the frame, a motorized nail is lengthened by a signal from a magnet.

[3] Of note, this bias may be unique to physicians in the United States where healthcare resources are more plentiful. In discussions with surgeons in developing countries, amputation is generally the default option as reconstruction is too costly and resource intense for the developing world health systems.

amputations.[xi] Orthopedic surgeons may not feel as technically proficient in performing amputations, and thus they may be less likely to offer it as an option.

In addition to a discomfort with performing amputations, orthopedic surgeons may have less experience discussing amputations and post-amputation recovery.[4] Discussing an amputation is always difficult, particularly when it is being considered for a previously active, healthy patients, as is the case with so many of these injuries. Surgeons' default setting is to do everything we possibly can to restore a limb to its pre-injury state, and amputation is antithetical to that. Amputation is permanent and irreversible, and orthopedic surgeons may lack knowledge and experience in having these conversations.

Additionally, there are other motivating factors that may encourage a surgeon to pursue reconstruction. From a personal perspective, I have derived tremendous satisfaction and joy from performing reconstructive surgery. The successful reconstruction of a near-complete amputation of the foot not only produced a happy patient, but also a publication.[xii] Surgeons are encouraged in the value of work with the frequent praise and gratitude most patients express to surgeons, even after a straightforward fracture surgery. In contrast, amputation is unlikely to lead to the same degree of thanks from patients, and instead be viewed as an unavoidable complication of the injury rather than an elegant reconstructive procedure.

[4] A notable exception to this may be the orthopedic oncology community, where discussion about amputation versus reconstruction is ingrained in the training and practice. However, I believe this conversation less frequent amongst the orthopedic trauma population, based on my personal experience and conversations with traumatologists at many other institutions. Within orthopedic training itself, there is limited education on patient-physician communication, and this may be another area that requires redress.

Finally, surgical reconstruction requires multiple surgeries and a prolonged hospitalization. This treatment course is more resource intense and therefore more lucrative to the physician and the hospital system. While I hope most physicians do not consider compensation when recommending treatment, there is clearly a financial incentive for reconstruction, and this may influence what treatment is recommended. Fears of tort litigation may also be a financial disincentive; [xiii] many tort attorneys advertise lawsuits for improperly amputated limbs.[5] Therefore, reconstruction may be incentivized both through increased compensation and decreased liability. Additionally, reconstruction does not eliminate the possibility of amputation, so proceeding with reconstruction as the default option doesn't seem to burn any treatment bridges.

There have been numerous publications over the past 20 years about the surgical outcomes for HELET injuries, but there has been a lack of similar research into the surgical decision-making about these injuries. Surgeons perform more reconstructions than amputation, in spite of equivalent functional outcomes. There are multiple possible reasons why surgeons may prefer reconstruction to amputation: training focus, surgical comfort, avoidance of difficult conversations, compensation and avoidance of litigation. Further study is needed to determine whether these reasons are driving the increased rates of reconstruction or if other unconsidered factors underly this treatment difference.

3.2. Patient Perspectives on Decision Making

[5] A simple web-search for "amputation lawsuit" yields 755,000 results.

Little is known about physician decision-making around reconstruction and amputation; there is similarly limited evidence on patient decision-making around reconstruction and amputation. Patients took part in the same standard gamble analysis survey as discussed above. Patients more strongly preferred reconstruction to primary amputation, giving a QALY of 30.43 for reconstruction versus 24.89 for primary amputation, and this difference was statistically significant with a P of 0.02.[xiv] Additionally, patients in this study anticipated significantly worse function than the physicians in the group, assigning utilities of 0.83 for reconstruction and 0.67 for amputation, while physicians assigned a utility of 0.97 for reconstruction and 0.95 for amputation. While this is only one study, it suggests that patients will strongly prefer reconstruction to amputation, believing that their function and activity will be dramatically better with reconstruction than amputation. This study also suggests a substantial gap in patient understanding as compared to the literature, and thus a need for patient education to ensure any decision about treatment is informed.

The same research group who performed the study above also conducted a qualitative analysis with semi-structured interviews on twenty patients with severe tibial fractures who underwent amputation or reconstruction.[xv] The authors found that many of the patients were incapacitated (sedated or medicated) and thus less involved in decision-making than their families. Those patients who underwent reconstruction believed their treatment was preferable because amputation was inevitably worse. This perspective matches with the utility analysis seen in patients who participated in the gambling analysis discussed above, where utility and QALY for amputation was considered much worse than reconstruction.

In contrast, those patients who underwent amputation had a different rationale. Rather than focusing on the outcome of amputation or reconstruction, the patients who underwent amputation instead felt that the path of reconstruction was "not worth it" or "successful reconstruction was deemed impossible to achieve."[xvi] Four of the eleven patients who underwent reconstruction and two of the five secondary amputation patients had second thoughts about whether the other treatment would have been better. Importantly, patients in both treatment categories "denied having a significant role in the decision making but described their surgeons as playing a major part in this process, by providing the treatment options and discussing the surgeons' willingness to perform any given surgical procedure." [xvii]

These studies provide some insight into patient preferences around HELET injuries, and patient's baseline preference for reconstruction. It also highlights the equivocal feelings of those whom have undergone reconstruction and amputation, and it raises questions about patient understanding about their injuries and anticipated outcomes. This limited work also supports the need for the development of a decision aid to help patients and their families understand their injuries and make more informed choices. Most importantly, it is unknown if patients' preference for reconstruction would be maintained if they had an improved comprehension of the long-term outcomes from the two treatment pathways.

4. The Harms of Reconstruction

In a well-known editorial in 1987, Sigvard Hansen MD, a world-famous orthopedic surgeon, advocated for early amputation in order to avoid the harms of reconstruction. "As a

result of managing open fractures in large numbers for the past twenty years in a center where sophisticated equipment and techniques have been available during most of that time, I have observed that very long treatment programs with accompanying multiple hospitalizations and operations are detrimental to many patients. By the time healing occurs, the final result is often marginal or worse than an early amputation would have been in terms of function and appearance. Moreover, the patient's life has often been drastically changed, and he or she may be demoralized, divorced or destitute." [xviii]

Patients who choose a reconstruction pathway instead of primary amputation[6] will have more operations and longer rehabilitation.[xix] In one study, patients who underwent reconstruction had an average of 8 surgeries and a prolonged hospitalization.[xx] This translates into weeks to months of hospitalization. Each surgery will generally require anesthesia and usually an intubation, where a breathing tube is inserted, and the patient is connected to a ventilator. Prolonged use of antibiotics, intravenous in the case of osteomyelitis (a bone infection), will be required to prevent or treat infection. The patient will spend most of the hospitalization in a single room, and visitors are often logistically limited.

Beyond the increased surgeries and time spent in the hospital, reconstruction also may require prolonged use of opioids, due to the repeat surgical procedures and thus re-initiation of the nociceptive pathway. Dr. Travis Rieder detailed his journey with a limb reconstructive procedure and his subsequent opioid dependence.[xxi] His journey is not unique. Unlike elective

[6] Primary amputation is generally defined as amputation during the initial hospitalization. This can include patients who sustain a traumatic amputation, where no replantation of the limb was required, but it also includes patients who may have had one or more initial stabilization surgeries, who then decide to pursue an amputation.

procedures, where multimodal analgesia is routine and the patient can be prepared for their experience, a limb-threatening trauma is unplanned by definition. Further, it is likely to cause anxiety and anxiety is correlated with pain.[xxii] It is reasonable to assume that these patients experience greater distress due to the psychological component of the injury, as they find their lives inexorably and irrevocably changed.

There is an additional potential harm of reconstruction beyond prolonged hospitalization, potential opioid dependence, and the "demoralized, divorced or destitute" concerns of Dr. Hansen.[xxiii] The reconstructive pathway creates a high likelihood that patients and/or physicians may succumb to the sunk cost fallacy. Individuals commit the sunk cost bias or fallacy when they continue to invest resources as a result of previously invested resources, even when these resources might be better used elsewhere.[xxiv] The reconstructive pathway for a HELET injury is long and requires significant investment by the patient. In interviews with patients who pursued limb reconstruction, there was evidence of patients using the sunk cost fallacy to justify continuing with unsuccessful treatment. For example, patients noted that they might be more functional with an amputation, but they were reluctant to consider an amputation due to years spent pursuing reconstruction.[xxv] What role, if any, the sunk cost fallacy might be playing in the decision to continue with reconstruction has not yet been studied, but I believe it is a significant risk and therefore must be considered as a potential harm of the reconstructive pathway.

The potential harm of the sunk cost fallacy is even more pronounced when considered in light of data from veterans. In combat-injured veterans, "after adjusting for covariates, early amputation was associated with reduced likelihood for wound complications, osteomyelitis,

musculoskeletal disorders, and some psychological disorders compared with late amputation or limb salvage. This was particularly evident during the first two years after injury."[xxvi] This study also found that veterans who underwent late amputation had the highest prevalence of psychological disorders, including mood, substance use, anxiety and tobacco use disorders, when compared to veterans who underwent early amputation and/or limb salvage. In the case of a HELET injury, the sunk cost fallacy will cost the patient more than the time investment; it also appears to increase the likelihood of physical and psychological comorbidities when delayed amputation is ultimately performed.

5. The Harms of Amputation

The harms of amputation may seem to be more straightforward than reconstruction. The loss of a limb is permanently disabling and may be accompanied by phantom limb pain. For the rest of their life, a patient will require a prosthetic or other assistive device for mobility. Additionally, their mobility will always be more limited than it was before the injury. A transtibial amputation (an amputation through the bone between the ankle and the knee) increases the energy expenditure of walking by 25%.[xxvii] While amputees may be able to run marathons, they spend much more energy to do so.

The true effects of amputation are difficult to quantify. To quote Dr. Burgess, "No amount of psychological testing and evaluation can completely measure the effects of limb loss on a given individual. Only the amputee knows what it is like to lose a limb and how that loss impacts their life."[xxviii]

In my experience, I have had had patients express a range of emotions around amputation. I had a patient in extreme distress about the traumatic amputation of the small toe from a lawnmower, stating he feels like "less of a man." Another patient with a lawnmower injury resulting in the same amputation said, "it's just a toe." While many patients will have high function and coping with an amputation, the potential for tremendous harm is real. For example, one patient stated: "I've always felt that if they woulda taken [my leg off] I'd probably commit suicide. That's how I feel about that."[xxix]

The cost of prosthetics may be another harm of amputation. While the immediate costs for limb reconstruction are greater than the initial costs of amputation, prosthetics are expensive. One study in 1994 showed that amputation was more expensive than reconstruction due to the prosthetic costs.[xxx] Further study is needed to determine if the lifetime costs of amputation are greater than the lifetime costs of reconstruction.

A final consideration about a possible harm of amputation is the potential for decisional regret. There is limited research into whether patients regret their decision for an amputation; the available evidence suggests that this is not a significant issue but it warrants further exploration.[xxxi] Jerome Groopman and Pamela Hartzband discussed "The Power of Regret" and components that lead to regret, including "imagining that the present situation would have been better if one had acted differently, and self-recrimination for having made a choice that led to a bad outcome."[xxxii] The decision for early amputation is one that could clearly include both components for a regretted decision, especially if the amputation had subsequent complications.

More research is needed into whether patients experience decisional regret after an amputation. Research is also needed as to whether secondary amputation for trauma is less harmful than the military study suggested.[xxxiii] There is evidence in the cancer literature that patients who had a secondary amputation after initial limb reconstruction surgery did not regret the attempted reconstruction, as it allowed them time to come to terms with the necessity of an amputation.[xxxiv] It may be that the harms of secondary amputation are more pronounced in the young, active military population, where a primary amputation permits more rapid return to work.

6. Failures in Framing the Conversation

Before discussing how physicians ought to frame the discussion around limb reconstruction and amputation, I would first like to state some ground rules for the decision-making process. I have previously written a more extended discussion on what physicians ought not do, and this section is largely derived from that work.[xxxv]

First, it is likely that the patient will ask the physician if they can "save the leg." In this situation, it is paramount that the physician purposefully avoids such messianic language. After a HELET injury, it is impossible for the physician to "save the leg" in the way the patient means, that is, a restoration to the pre-injured state. If the physician mirrors the patient's language, they are establishing unrealistic expectations and failing to be honest about the known outcomes. This may be a particular challenge, as orthopedic training is focused on restoration to the uninjured state, and this is not possible after a high-energy, lower extremity trauma. Additionally, many physicians may have been trained to see amputation as a failure. As one of my mentors used to

say, “An amputation is a great surgery, but you have to try something cool first.” If we tell a patient we can “save the leg” we are likely to cause them harm over the long term, as they slowly discover what we knew all along—the leg we “save” is a completely different leg than they had before the trauma.

Additionally, as amputation and reconstruction have equivalent outcomes, both should be offered as a treatment option. Amputation should not be offered as an option only if reconstruction fails, especially in light of the evidence of worse outcomes with secondary amputation after failed reconstruction.[xxxvi] The two-year outcomes are equivalent between the two treatment options, creating a situation of clinical equipoise. Shared decision-making is key in times of clinical equipoise. The American Academy of Orthopaedic Surgeons Clinical Practice Guidelines emphasizes the importance of shared decision-making.[xxxvii]

A failure to discuss amputation would be analogous to a surgeon failing to discuss mastectomy for a patient with breast cancer, and instead only discussing breast preserving surgery and radiation. For a patient with breast cancer, there are multiple decision aids to enhance patient autonomy and decision-making about treatments.[xxxviii] These decision aids provide information on the treatment options, anticipated outcomes, as well as the pros and cons of each treatment. There is no similar decision aid for patients with a HELET injury, and as such it is particularly incumbent upon the treating physician to ensure the patient understands the gravity of their injury, treatment options, treatment course and anticipated outcomes.

These “ground rules” for discussing amputation should be non-controversial and easy for most physicians to accept. It is difficult to argue that patients should not be informed of the option of amputation, or that physicians ought to promise to “save the leg” when there is no evidence that they can maintain such a promise. It seems obvious that patients should always be told about the anticipated outcomes and supported as they make a decision. Yet, I feel obligated to include these “ground rules” as my experience has shown that not all patients are afforded this minimum standard as they make decisions about their extremity injuries. For example, my colleague had a limb threatening injury and was told by the surgeon that the surgical team would do everything they could to “save his foot,” and amputation was never offered as an option. Further, the surgeon did not counsel my colleague that “saving the foot” would not equate to having the old foot.[xxxix]

7. How Should We Move Forward?

There is much we don’t know about limb threatening injuries. We lack a nuanced understanding of how patients and physicians make decisions about treatment. We have limited knowledge about the financial costs of the two approaches. There is no decision-aid to support shared decision-making. We need to learn more about the patient experience for both the reconstructive and amputation pathway.

Nevertheless, there is strong evidence to support equivalent outcomes between amputation and reconstruction at two years after injury. Therefore, it would seem reasonable that physicians must offer both amputation and reconstruction to their patients as a treatment option,

and let the patient decide on their path. Yet, it is important to understand that it takes two, hard years to reach a point at which outcomes are finally equivalent. Patients cannot fast forward through the first two years of their recovery; and for those two years, patients who choose reconstruction have a demonstrably more difficult path. These patients spend more time in the hospital and have more surgeries. They are delayed with ambulation and they will spend more time away from their families. They may become opioid dependent. They will be delayed in receiving a disability rating due to their prolonged course and this can have financial implications. While there are clearly harms of amputation, as discussed above, it would seem that the harms of recovery from reconstruction make amputation a less harmful (that is, better) option for many patients.[7]

Additionally, primary amputation will avoid the dangers of the sunk cost fallacy. While surgeons may prefer to "do something cool first" before amputation, for the patient undergoing the "something cool" the likelihood of needing amputation may become more and more opaque. Further, the patient may not view this as a last gasp effort, but instead as an inevitably successful treatment.

Finally, the harm of amputation is greatest when one compares the harm of amputation to a normal, uninjured limb. When one compares an amputation to a reconstructed extremity after a high-energy trauma, the harms are greatly reduced. It is illogical to compare amputation to a normal limb, as the injury itself has forever removed the possibility of a "normal limb." As such,

[7] There are patients, as discussed in the "harms of amputation" section who view amputation as such an evil that they would contemplate suicide. The argument about the harms of amputation can't fully account for these outlier patients, as anyone feels that suicide would be a reasonable option if amputation must be pursued clearly will have greater harms from amputation than reconstruction.

the functional deficits from an amputated extremity should not be compared to a healthy limb but rather to the limb post-reconstruction.

For all these reasons, the harms of reconstruction are greater than the harms of amputation for the majority of patients. Therefore, a physician's obligation to support their patient's best interest goes beyond a duty to discuss amputation as a treatment option; physicians have an obligation to promote amputation, recommending it as a treatment option.

Importantly, I am not arguing that physicians disregard discussions of reconstruction. This would clearly be a failure to support informed decision-making in the same way that a physician failing to offer amputation as a treatment option and only framing amputation as a surgery to be performed if reconstruction fails is a failure of informed consent. Instead, physicians must explain to their patients that amputation and reconstruction have equivalent outcomes at two years, but if they pursue amputation, they will have fewer hospitalizations, shorter recovery time, and likely improved psychologic outcomes,[8] and as such surgeons should recommend amputation as the treatment for these injuries. This recommendation should be a nudge, not a push, towards amputation. I have spoken with many surgeons about what treatment they would want after a HELET injury, and universally my colleagues say they would want an amputation. If and when the patient asks the surgeon about what they would do, the surgeon should answer honestly, providing reasons for their choice as appropriate. For example, if I were to sustain a HELET injury, I would personally opt for amputation in order to minimize my time

[8] The military studies have demonstrated improved psychological outcomes, but there is no literature within the civilian population on this yet.

in the hospital and under treatment in order to more readily return to my family, my work, and exercise.

Those who oppose amputation and prefer limb reconstruction might argue that amputation is disfiguring and final; patients are unable to choose to return to a limb reconstruction pathway after they opt for an amputation in the same way they can choose amputation if they first opt for reconstruction. Clearly, I cannot argue that amputation is anything other than final and irreversible. Yet, it is also true that a HELET injury is itself disfiguring and final. Further, studies from the military demonstrate that secondary amputations have worse outcomes than primary amputation. As such, even if one ignores the time and opportunity costs of an unsuccessful pursuit of reconstruction, secondary amputation is still clearly more harmful than primary amputation.

Others might argue that at the time of initial injury we do not always know the patient's injury score and their likelihood of attaining high function. Yet, studies have shown that injury scoring systems should not be the basis for limb reconstruction.[xl] While physicians may prefer to defer difficult decisions to another day, we have excellent literature defining which injuries should be categorized as a HELET injury and therefore anticipated to have equivalent outcomes with reconstruction or amputation. Further, given that our training generally biases us towards reconstruction, it is highly unlikely that there would ever be a seismic shift and surgeons begin to pursue amputation for limbs that would be better treated with reconstruction.

The lack of surgeon training in amputations is not an argument against counseling for amputation; instead, it is an argument to increase physician's training and competency in order to better care for our patients. Likewise, the potential discomfort of many orthopedic surgeons around amputation is not an argument to pursue reconstruction. Instead, it is a reason to increase training and knowledge about how to have these conversations.

It is likely that even if surgeons begin to promote amputation, many patients will still prefer to pursue reconstruction. In fact, it would be surprising if this weren't to be the case, based on the evidence we have of patient preference for reconstruction.[xli] Promoting amputation as a treatment option still allows patients to choose the treatment concordant with their own preferences and desires. Yet, it is also likely to destigmatize amputation as a treatment option for the patient, appropriately reframing amputation as a treatment choice rather than a procedure for when all else fails. Importantly, this reframing may also help prevent patients from pursuing reconstruction before their sunk costs become too great.

8. Practical Considerations

While I have argued that promoting amputation is in most patients' best interests, I recognize that such a reframing may be difficult for many physicians. Despite this difficulty, I believe it is important and necessary. In order to enhance patient decision-making, I would advocate for the development of a decision aid for patients who sustain a HELET injury. It is likely that many patients pursue reconstruction without full autonomy, as they lack understanding about what reconstruction entails. A decision aid would support patients as they

make a decision about treatment. The decision aid would discuss the pros of surgical reconstruction (e.g. a prosthetic is not required), cons of surgical reconstruction (e.g. a longer hospital course), the pros of amputation (e.g. a faster recovery with equal functional outcomes), and the cons of amputation (e.g. phantom limb pain). The decision aid would include visual aids to help patients with decision making, e.g. images of prosthetics and external fixator frames. The decision aid would help patients understand the recovery process and help patients discuss their treatment plan with their care team.

Additionally, peer support should be pursued wherever possible. The improved outcomes for amputees in the military may be due to the increased support and service member relationships. When possible, it is ideal for patients to be able to meet and talk to other patients who have already gone through a reconstructive or amputation pathway. For example, one patient reported, "And I just met a new young man who had 20 surgeries [with unsuccessful reconstruction] and he finally had the leg removed and he said, 'I am so much better off.' So I feel that I did make the right decision."[xlii] Peer support for either treatment decision can help patients better understand what each treatment pathway entails.

I have previously argued that physicians should take a damage control approach to the conversation around HELET injuries, similar to the "damage control orthopaedics" approach that surgeons employ for severe trauma.[xliii] This approach advocates initial cleaning of the wound and stabilization with a splint or fixator to prevent the bone from moving, followed by an early discussion of treatment options. The injury is emotionally distressing and following a major trauma, the patient will likely be in a fight or flight response physiologically and

psychologically. At this time, initial stabilization should be the goal, allowing the patient to transition into a less acute state as they consider treatment options. While this may not always be possible, when possible it will support autonomy by allowing more careful consideration of treatment options. This brief delay/staged approach may also permit the patient, rather than their family, to be the primary decision maker as the patient may be sedated due to other injuries or incapacitated by opioids at the initial discussion.

9. Conclusion

Ultimately, good ethics requires good evidence, and while there has been extensive study of these injuries, significant gaps remain. There is a dearth of research into the lifetime costs of each pathway, as well as limited research into the long-term outcomes and adverse outcomes of each treatment pathway. The psychological impacts of each treatment are woefully understudied, and there is a need for qualitative studies evaluating more than physical function. However, given what we do know, there is good reason to believe that surgeons have been under-selling the benefits of amputation, and instead pursuing limb reconstruction without adequate patient input and understanding. The patient's best interests—shorter recovery, faster weightbearing, quicker return to work, decreased risk of opioid dependence, decreased hospitalizations—favor amputation as the preferred treatment course. While many patients will still prefer reconstructions, surgeons will better support their patients best interests by promoting amputation in the conversation about a high-energy, lower extremity trauma. Perhaps most importantly, a shared-decision aid would greatly enhance patient decision-making and permit truly shared-decision making.

Bibliography

[i] Bosse MJ, MacKenzie EJ, Kellam JF, Burgess AR, Webb LX, Swiontkowski MF, Sanders RW, Jones AL, McAndrew MP, Patterson BM, McCarthy ML, Travison TG, Castillo RC. An Analysis of Outcomes of Reconstruction or Amputation of Leg-Threatening Injuries. The New England Journal of Medicine. 2002; 347(24): 1924-1931.

[ii] Bosse MJ, 2002.

[iii] Hertel R, Strebel N, Ganz R. Amputation versus reconstruction in traumatic defects of the leg: outcome and costs. J Orthop Trauma. 1996;10:223–229.

Hoogendoorn JM, van der Werken C. Grade III open tibial fractures: functional outcome and quality of life in amputees versus patients with successful reconstruction. Injury. 2001;32:329–334.

Bosse MJ, 2002.

MacKenzie EJ, Bosse MJ, Kellam JF, et al. Factors influencing the decision to amputate or reconstruct after high-energy lower extremity trauma. *J Trauma*. 2002;52:641–649.

[iv] Parrett BM, Matros E, Pribaz JJ, et al. Lower extremity trauma: trends in the management of soft-tissue reconstruction of open tibia-fibula fractures. *Plast Reconstr Surg*. 2006;117:1315–1322.

[v] Swiontkowski MF, MacKenzie EJ, Bosse MJ Jones AL, Travison T for the LEAP Study Group. Factors Influencing the Decision to Amputate or Reconstruction after High-Energy Lower Extremity Trauma. The Journal of Trauma, Injury, Infection and Critical Care. 2002;52:641-649.

[vi] Major Extremity Trauma and Rehabilitation Consortium and the American Academy of Orthopaedic Surgeons. Clinical Practice Guideline for Limb Salvage or Early Amputation, Adopted by the American Academy of Orthopaedic Surgeons Board of Directors December 6, 2019.

[vii] Hebert J, Mayank R, Stiegelmar R. Osseointegration for Lower-Limb Amputation A Systematic Review of Clinical Outcomes. J Bone Joint Surg Reviews. 2017; 5(10): e10. Doi: 10.2106/JBJS.RVW.17.00037

[viii] Parrett BM, Matros E, Pribaz JJ, et al. Lower extremity trauma: trends in the management of soft-tissue reconstruction of open tibia-fibula fractures. *Plast Reconstr Surg*. 2006;117:1315–1322.

[ix] Major Extremity Trauma and Rehabilitation Consortium and the American Academy of Orthopaedic Surgeons. Clinical Practice Guideline for Limb Salvage or Early Amputation, Adopted by the American Academy of Orthopaedic Surgeons Board of Directors December 6, 2019.

[x] Hasler CC, Krieg AH. Current Concepts of Leg Lengthening. J Child Orthop. 2012; 6(2):89-104

[xi] Ferrendelli B. Are Orthopedic Surgeons Leaving the Amputation Healthcare Team? September 2012 Issue. "The O&P Edge." *https://opedge.com/Articles/ViewArticle/2012-08-23/2012-09_03 [Accessed April 13, 2020]*

[xii] Retzky JS, Humbyrd CJ. Near-Complete Traumatic Amputation of the Forefoot After Motorboat Propeller Injury. Foot and Ankle Orthopaedics. 2019. https://doi.org/10.1177/2473011418822278

[xiii] Hansen ST. Editorial: The Type-IIIC Tibial Fracture. The Journal of Bone and Joint Surgery, American Volume. 1987; 69A(6):799-800.

[xiv] Chung KC, Shauver MJ, Saddawi-Konefka, D, Haase SC. A Decision Analysis of Amputation Versus Reconstruction for Severe Open Tibial Fracture from the Physician and Patient Perspectives. Annals of Plastic Surgery. 2011; 66(2): 185-191.

[xv] Aravind M, Shauver MJ, Chung KC. Q Qualitative Analysis of the Decision-Making Process for Patients with Severe Lower Leg Trauma. Plastic and Reconstructive Surgery. 2010; 126(6):2019-2029.

[xvi] Aravind M, 2010.

[xvii] Page 2025. Aravind M, 2010.

[xviii] Hansen ST, 1987.

[xix] Hertel R, 1996

Hoogendoorn JM, 2001.

Bosse MJ, 2002.

MacKenzie EJ, 2002.

[xx] Hertel R, 1996.

[xxi] Rieder, Travis. *In Pain: A Bioethicists Personal Struggle with Opioids*. New York, New York, Harper Collins, 2019.

[xxii] Park S, Na SH, Oh J, Lee JS, Oh ST, Kim JJ, Park JY. Pain and anxiety and their relationship with medication doses in the intensive care unit. J Crit Care. 2018; 47:65-69. doi: 10.1016/j.jcrc.2018.05.014.

[xxiii] Hansen ST, 1987.

[xxiv] Arkres HR, Blumer C. The psychology of sunk cost. Organizational Behavior and Human Decision Processes. 1985; 35(1):124-140. https://doi.org/10.1016/0749-5978(85)90049-4
[xxv] Unpublished interviews from the METRC study.
[xxvi] Melcer T, Walker J, Bhatnagar V, Richard E, Sechriest VF, Galarneau M. A Comparison of Four-Year Health Outcomes following Combat Amputation and Limb Salvage. PLoS One. 2017; 12(1):e0170569.
[xxvii] https://www.orthobullets.com/trauma/1052/amputations [Accessed 15 April 2020]
[xxviii] Reference to edition 1, 1981. Available at: https://orthop.washington.edu/patient-care/limb-loss/general-principles-of-amputation-surgery.html [Accessed 15 April 2020]
[xxix] Page 2027. Aravind M, 2010
[xxx] Williams MO. Long-term cost comparison of major limb salvage using the Ilizarov method versus amputation. Clin Orthop Relat Res. 1994; 301:156-8.
[xxxi] Aravind M, 2010.
[xxxii] Groopman J, Harzband P. The Power of Regret. The New England Journal of Medicine. 2017. 377;16: 1507-9.
[xxxiii] Melcer T, 2017.
[xxxiv] Eiser C, Darlington A-S E, Stride CB, Grimer R. Quality of life implication as a consequence of surgery: limb salvage, primary and secondary amputation. Sarcoma. 2001; 5, 189-195.
[xxxv] Humbyrd CJ, Rieder, TN. Ethics and Limb Salvage: Presenting Amputations as a Treatment Option in Lower Extremity Trauma. J Bone Joint Surg Am. 2018; 100(19):e128. doi: 10.2106/JBJS.17.01522.
[xxxvi] Melcer T, 2017.
[xxxvii] Major Extremity Trauma and Rehabilitation Consortium and the American Academy of Orthopaedic Surgeons. 2019.
[xxxviii] https://decisionaid.ohri.ca/AZsearch.php?criteria=breast+cancer [Accessed 16 April 2020]
[xxxix] Humbyrd, 2018.
[xl] Major Extremity Trauma and Rehabilitation Consortium and the American Academy of Orthopaedic Surgeons. 2019.
[xli] Chung KC, 2011.
[xlii] Page 2026. Aravind M, 2010.
[xliii] Humbyrd, 2018.

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